

FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

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CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

CONKWEST, INC.)
The Plastino Building)
2533 South Coast Highway 101, Suite 210)
Cardiff-by-the-Sea, CA 92007-2133,)
Plaintiff,)
v.)
HON. MARGARET A. FOCARINO,)
performing the functions and duties of Under)
Secretary of Commerce for Intellectual Property)
and Director of the United States Patent and)
Trademark Office)
P.O. Box 1450, Alexandria, VA 22313-1450)
Defendant.)

Civil Action No. 1:13cv1566-GBL/KB

COMPLAINT

Plaintiff Conkwest, Inc. (“Conkwest”), for its Complaint against Defendant, the Acting Director of the United States Patent and Trademark Office (“PTO”), alleges as follows:

I. NATURE OF THE ACTION

1. This civil action is brought pursuant to 35 U.S.C. § 145 by the assignee of U.S. Patent Application Serial No. 10/008,955 (“the ’955 application”), Plaintiff Conkwest, against the Acting Director of the PTO seeking a judgment that Plaintiff is entitled to a patent for the invention specified in claims 20, 26, and 27 of the ’955 application, which claims are the subject of a final decision by the Patent Trial and Appeal Board (“PTAB”).

2. This civil action arises under 35 U.S.C. § 145 because Plaintiff Conkwest, to whom the applicant’s rights in the ’955 application have been assigned, is dissatisfied with the

final decision of the PTAB in an appeal under 35 U.S.C. § 134(a) affirming the rejection of claims 20, 26, and 27 of the '955 application.

II. THE PARTIES

3. Plaintiff Conkwest is a corporation organized under the laws of the State of Illinois and has its principal place of business at 2533 South Coast Highway 101, Suite 210 Cardiff-by-the-Sea, CA 92007-2133.

4. Defendant Margaret A. Focarino is the Commissioner for Patents and, as of November 21, 2013, has been performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the PTO, a position that is currently vacant. Defendant Focarino is sued in her official capacity.

5. On December 11, 2013, the U.S. Secretary of Commerce Penny Pritzker announced the appointment of Michelle K. Lee as the next Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the PTO. The announcement states that Ms. Lee will begin her new position on January 13, 2014.

III. JURISDICTION AND VENUE

6. This Court has jurisdiction and venue pursuant to 35 U.S.C. § 145 (as amended by the America Invents Act on September 16, 2011).

7. The PTAB decision was rendered by a three-judge panel on October 25, 2013. The PTAB decision was a final decision under 37 C.F.R. § 41.2. This Complaint is being timely filed, within sixty-three (63) days of the final decision, in accordance with 37 C.F.R. § 90.3(a)(3)(i).

8. Plaintiffs have not appealed the final decision of the PTAB at issue in this civil action to the United States Court of Appeals for the Federal Circuit.

9. Jurisdiction in this civil action is limited to claims 20, 26, and 27 of the '955 application, which claims were the only claims held unpatentable in the PTAB's final decision.

IV. BACKGROUND

10. Hans Klingemann, M.D., Ph.D, ("Applicant") is the sole inventor named on the '955 application, titled "Natural Killer Cell Lines and Methods of Use," filed December 7, 2001. The '955 application is a continuation-in-part of U.S. Patent Application Serial No. 09/403,910, filed October 27, 1999, which is a national phase application of International Application Serial No. PCT/US98/08672, filed April 30, 1998, which claims the benefit of U.S. Provisional Patent Application Serial No. 60/045,885, filed April 30, 1997.

11. The '955 application discloses and claims a method of treating a cancer *in vivo* in a mammal using a particular cell line, NK-92, invented by Applicant Klingemann.

12. Plaintiff Conkwest is the assignee of the '955 application, as evidenced by records recorded in the PTO, and is the real party-in-interest in this case.

13. On June 6, 2002, prior to any examination on the merits, the PTO published the '955 application, thereby permitting the public to read the full contents of the '955 application since June 6, 2002.

14. On January 27, 2005, more than three years after the '955 application was filed, and having not received an examination on the merits of the invention, Applicant sent a "Status Inquiry" to the PTO noting that "[t]o date, Applicant[] ha[s] not received an Official Action on the merits." Applicant further noted that "[n]o other communications have been received from the Patent and Trademark Office indicating action on this application since the Notice of Publication" of the '955 application. Applicant therefore requested the PTO to "advise the undersigned [attorney of Applicant] of the present status of this application."

15. On September 7, 2006, the PTO, through Primary Examiner Ronald Schwadron, mailed a Restriction Requirement requiring Applicant to elect only a single group of claims to be examined on the merits. The Examiner required an election of one of: Group I claims (claims 1-9), Group II claims (claims 10-19), or Group III claims (claims 20-29).

16. On October 6, 2006, Applicant duly filed a response to the Restriction Requirement in which Applicant elected the claims of Group III (claims 20-29) for examination on the merits, and withdrawing the claims of Groups I and II (claims 1-19) from consideration.

17. On December 28, 2006, rather than addressing the patentability of elected claims 20-29 on the merits, Examiner Schwadron mailed a second Restriction Requirement requiring Applicant to elect, from among claims 20-29, only a “single disclosed species for prosecution on the merits.” In particular, the Examiner required an election of one of: Species A (“method of treating a cancer or a pathogenic virus”), or Species B (“method using cells wherein HLA expression has been inhibited or wherein the cells have been transfected with a vector encoding a cytokine or the cells of claim 28”).

18. On April 27, 2007, Applicant duly filed a response to the second Restriction Requirement in which Applicant elected Species A related to treating cancer as claimed in claims 20, 22, 23, 26, and 27 for examination on the merits, and withdrawing claims 21, 24, 25, 28, and 29 from consideration. Applicant amended claim 20 to comply with the Examiner’s election requirement. Applicant also added new claims 30 and 31, which recite a method of treating cancer described in claim 22 wherein the cancer is a “solid tumor” or “non-solid tumor,” respectively.

19. On June 5, 2007, nearly five and a half years since the filing of the ’955 application, the PTO mailed a first Office Action on the merits of Applicant’s invention in which

Examiner Schwadron notified Applicant for the first time that claims 20, 22, 23, 26, 27, 30 and 31 were rejected as not patentable. The claims of the '955 application were rejected on the following grounds:

- a. Claims 20, 22, 23, 26, 27, 30 and 31 were “provisionally” rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending U.S. Patent Application No. 10/701,359.
- b. Claims 20, 22, 23, 26, 27, 30 and 31 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention.
- c. Claim 31 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
- d. Claims 20, 22, 23, 26, 27, 30 and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over a journal article authored by Gong et al., *Characterization of a Human Cell Line (NK-92) with Phenotypical and Functional Characteristics of Activated Natural Killer Cells*, 8 LEUKEMIA 652-658 (1994) (“Gong”), in view of U.S. Patent No. 5,272,082 issued to Santoli *et al.* (“Santoli”).

20. Applicant Klingemann is one of the authors of the Gong article.

21. On October 5, 2007, Applicant filed an Amendment and Response to the first Office Action. Applicant amended claim 20 to indicate that the claimed NK-92 cells are “available from American Type Culture Collection (ATCC) as Deposit No. CLR-2407.” Applicant also amended claim 31 to specify that the non-solid tumor is “of circulating cells.” Responding to the rejection under 35 U.S.C. § 103(a), Applicant explained why he believed that Gong in view of Santoli did not render obvious claims 20, 22, 23, 26, 27, 30 and 31.

22. On December 19, 2007, rather than addressing the patentability of the previously-elected claims on the merits, Examiner Schwadron mailed a third Restriction Requirement requiring Applicant to elect, from among previously-elected claims 20, 22, 23, 26, 27, 30 and 31, only a single species drawn to either solid or non-solid circulating cells. The Examiner stated that these two “species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species” and that “these species are not obvious variants of each other based on the current record.”

23. On January 17, 2008, Applicant duly filed a response to the third Restriction Requirement in which Applicant elected to prosecute the invention drawn to treating a “solid tumor” as claimed in claim 30, and withdrawing claims 23 and 31 drawn to treating a non-solid tumor.

24. On April 15, 2008, Examiner Schwadron mailed a Final Office Action rejecting claims 20, 22, 26, 27 and 30. The claims of the '955 application were rejected on the following grounds:

a. Claims 20, 22, 26, 27 and 30 were “provisionally” rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending U.S. Patent Application No. 10/701,359.

b. Claims 20, 22, 26, 27 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gong in view of Santoli.

25. On October 15, 2008, Applicant filed a Request for Continued Examination, accompanied by the Declaration of Hans Klingemann, M.D., Ph.D., to provide an expert opinion explaining why claims 20, 22, 26, 27 and 30 would not have been obvious under 35 U.S.C. § 103(a) over Gong in view of Santoli.

26. On March 24, 2009, Examiner Schwadron mailed a Final Office Action rejecting claims 20, 22, 26, 27 and 30 on the same grounds as those in the Final Office Action dated April 15, 2008.

27. On September 15, 2009, Applicant filed a notice of appeal from the Examiner to the Board of Patent Appeals and Interferences (now the PTAB).

28. On March 23, 2010, Applicant filed an Appeal Brief in support of the appeal.

29. On July 9, 2010, after first requiring Applicant to resubmit the Appeal Brief to fix minor clerical errors found by Examiner Schwadron, Examiner Schwadron *sua sponte* reopened prosecution by mailing a non-final Office Action, thereby terminating Applicant's appeal. Examiner Schwadron again rejected claims 20, 22, 26, 27 and 30. The claims were rejected on the following grounds:

a. Claims 20, 22, 26, 27 and 30 were "provisionally" rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending U.S. Patent Application No. 10/701,359.

b. Claims 20, 22, 26, 27 and 30 were rejected under 35 U.S.C. § 112, first paragraph, as failing to enable a person of ordinary skill to make and use the invention.

c. Claims 20, 22, 26, 27 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gong in view of Santoli.

30. On October 12, 2010, Applicant filed an Amendment and Response to the non-final Office Action dated July 9, 2010. Applicant cancelled claim 22 and amended claim 20 to specify that the cancer is recognized and lysed by the NK-92 cell line.

31. On December 20, 2010, Examiner Schwadron mailed a Final Office Action rejecting claims 20, 26, 27 and 30. The Examiner withdrew the rejection under 35 U.S.C. § 112, first paragraph, but maintained the other two rejections.

32. On March 18, 2011, Applicant once again appealed from the Examiner by filing a Notice of Appeal with the Board of Patent Appeals and Interferences (now the PTAB).

33. On June 20, 2011, Applicant filed an Appeal Brief in support of this second appeal.

34. On October 21, 2011, Examiner Schwadron mailed an Examiner's Answer responding to Applicant's Appeal Brief.

35. On January 9, 2013, after more than a year and a half since the filing of Applicant's Appeal Brief in this second appeal, and having received no communication from the PTAB since the second appeal was docketed on January 27, 2012, Applicant filed a "Request for Status" with the PTAB requesting a status update.

36. On October 25, 2013, after more than 11 years and 10 months since the filing of the '955 application, the PTAB issued a "Decision On Appeal" affirming-in-part and reversing-in-part the Examiner's December 20, 2010 Final Office Action. In its Decision On Appeal, the PTAB held as follows:

a. The "provisional" rejection of claims 20, 26, 27 and 30, on the ground of nonstatutory obviousness-type double patenting, was "render[ed] . . . moot" by an express abandonment of the copending U.S. Patent Application No. 10/701,359.

b. The rejection of claims 20, 26, and 27 under 35 U.S.C. § 103(a) over Gong in view of Santoli was affirmed, but based on new reasoning from that proffered by Examiner Schwadron.

c. The rejection of claim 30 under 35 U.S.C. § 103(a) over Gong in view of Santoli was reversed.

V. SOLE COUNT

37. Plaintiff incorporates by reference the allegations in paragraphs 1-36 above, as if fully set forth here.

38. The decision of the PTAB, affirming the rejection of claims 20, 26, and 27 of the '955 application under 35 U.S.C. § 103(a) over Gong in view of Santoli, was unwarranted by the facts, was unsupported by substantial evidence, was in excess of statutory jurisdiction, authority or limitation, and was arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law.

39. Specifically, the PTAB (a) failed to establish a *prima facie* case of obviousness, (b) failed to give proper consideration to evidence demonstrating that the claimed treatment method would not have been obvious, and (c) applied incorrect legal standards in ascertaining whether claims 20, 26, and 27 of the '955 application would have been obvious over Gong in view of Santoli.

40. Claims 20, 26, and 27 of the '955 application are patentable and satisfy, *inter alia*, 35 U.S.C. § 103(a) as well as applicable statutory and regulatory requirements, and a United States Patent should issue thereon.

41. Upon allowance of claims 20, 26, and/or 27 of the '955 application, Plaintiff is entitled under 37 C.F.R. § 1.141 to consideration of any claim written in dependent form which includes all the limitations of claims 20, 26, and/or 27 of the '955 application, and a United States Patent should issue thereon.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays as follows:

- A. Entry of judgment setting aside and reversing the PTAB's conclusion, and the actions and findings underlying the conclusion, that claims 20, 26, and 27 of the '955 application are unpatentable under 35 U.S.C. § 103(a) over Gong in view of Santoli.
- B. For a decree pursuant to 35 U.S.C. § 145, authorizing the Director of the PTO to issue a United States Patent for the invention specified in claims 20, 26, and 27 of the '955 application, and any dependent claims satisfying 37 C.F.R. § 1.141, in due form of law, as prescribed by the Patent Statute, 35 U.S.C. § 1 *et seq.*
- C. For such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Dated: December 20, 2013

Respectfully submitted,


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